Table 3

COMPOSITION	AMOUNT IN 1 LITER
Sodium Gluconate	Approx 80mM
KH_2PO_4	Approx 25mM
Mg Gluconate	Approx 5mM
Adenine	Approx 5mM
Ribose	Approx 5mM
$CaCl_2$	Approx 0.5mM
HEPES	Approx 10mM
Glucose	Approx 10mM
Mannitol	Approx 30mM
Pentastarch	Approx 50g/L
Prostaglandin E1	Approx 500mcg/L
Nitroglycerin	Approx 5mg/L
N-Acetylcysteine	Approx 1mg/L
Sterile Water	Approx 800mL

[0023] A machine perfusion solution of the invention may be prepared by combining the components described above with sterile water, such as distilled and/or deionized water. For example, to prepare the solution, approximately 700-900mL, or preferably about 800 mL, of sterile water is poured into a one liter beaker at approximately room temperature. Although a one liter beaker is used in this example, any other container of any size may be used to prepare the solution, where the component amounts would be adjusted accordingly. In the most preferred embodiment, the following are added, in any order, to the solution and each is mixed until dissolved in the solution: approximately 80 mol/L sodium gluconate, approximately 25 mol/L potassium phosphate, approximately 5 mol/L adenine, approximately 5 mol/L of ribose, approximately 0.5 mol/L of calcium chloride, and approximately 50 g modified pentastarch. The

modified pentastarch is a fractionated colloid mixture of 40-60 kDaltons in diameter and is modified by infusing the pentastarch under 3 atm of pressure through a dialyzing filter with a bore size of about 40-60 kDaltons. About 5 mol/L magnesium gluconate, approximately 10 mol/L HEPES, approximately 10 mol/L glucose, and approximately 30 mol/L mannitol are also added, in any order, and mixed. Approximately 40 U of insulin is also added. Then, in a second step, approximately 1 mg of N-acetylcysteine, approximately 5 mg nitroglycerin, and approximately 500 mcg of modified prostaglandin E1 (PGE1) are added, in any order, to the solution. PGE1 is modified by centrifuging PGE1 under hypothermic conditions at 30K rpm and then filtering the resulting mixture through a 0.05 micro filter. The modified PGE1 has a half-life lengthened by a multiple of about 15. To adjust the pH of the solution to about 7.2-7.5, or preferably, 7.4 +/- 0.1, 5N KOH or NaOH is added, as needed. The first and second step may also be reversed.

[0024] The invention also provides a method for preserving an organ or biological tissue. The method includes pouring the machine perfusion solution into a chamber that mimics a deep hypothermic environment or physiological environment and moving the machine perfusion solution continuously through the chamber. The machine perfusion solution is infused in a mechanical fashion through the arterial or venous vascular system of cadaveric or living donor organs, or infused over or through an avascular biological substance in order to maintain organ or tissue viability during the ex vivo period. Preferred temperatures range from about 2-10°C in the deep hypothermic condition and are about 37°C, or room temperature, in the physiological condition. Use of this solution provides for the serial assay of solution over time to determine hydrostatic and chemical changes. These hydrostatic and chemical changes provide a mechanism to determine the functional viability of the organ or tissue once it has been returned to physiologic conditions.

[0025] The invention further provides a perfusion machine comprising a chamber that mimics a deep hypothermic environment or physiological environment, where the machine perfusion solution continuously moves through the chamber. Any perfusion machine that is known in the

art may be used with the solution, including machines providing pulsatile, low flow, high flow, and roller flow perfusion. Typically, the perfusion machine includes a unit for the static monitoring or transportation of organs or biological tissues and a cassette, or chamber, used to circulate perfusate through the organs or biological tissues. A monitor displays pulse pump rate, perfusate temperature, systolic, mean, and diastolic pressure, and real-time flow. Once such machine is the RM3 Renal Preservation System manufactured by Waters Instruments, Inc.® As discussed above, preferred temperatures range from about 2-10°C in the deep hypothermic condition and are about 37°C, or room temperature, in the physiological condition.

[0026] The invention is further explained by the following of examples of the invention as well as comparison examples. In all of the examples, kidneys were procured from heart-beating donors and preserved in a laboratory by cold storage preservation. Randomization was accomplished as an open labeled, sequential analysis. All agents were added immediately prior to vascular flush.

Data Collected

[0027] The following donor, preservation, and postoperative recipient outcome data were collected for either Example 1 or Example 2: donor age (D age, years), final donor creatinine (D Cr, mg/dL), donor intraoperative urine output (U/O, mL), cold ischemic time (CIT, hours), perfusion time (PT, hours), perfusate [Na+] (mM/100g), perfusate [C1-] (mM/100g), perfusate [K+] (mM/100g), perfusate [Ca++] (mM/100g), perfusate pH, renal flow during MP (FL, mL/min/100g), renal resistance during MP (RES, mmHg/(mL/min/100g), recipient age (R age, years), recipient discharge creatinine (R Cr, mg/dL), initial length of recipient hospital stay (LOS, days), immediate graft function (IF, %) defined as urine production exceeding 2000 mL during the first 24 post-operative hours, delayed renal allograft graft function (DGF, %) defined as the need for dialysis within the first 7 days post-transplant, and present function (3 Mo or 1 Yr., %) defined as 3 month or one year post-operative graft status.